REMARKS

Claims 1-8 and 11-14 were pending in the present application. Claims 1-7, 11 and 12 were rejected. Claims 1 and 14 are herein amended. Claims 2-6 and 11-13 are herein cancelled without prejudice. Claim 15 is herein added. No new matter has been added. Applicants thank Examiners Gudibande and Kosar for the courtesies extended in the telephone interviews of January 15, 2009 and January 21, 2009.

Preliminary Comments

Applicants herein amend the claims and provide a replacement sequence listing in order to fully comply with the U.S.P.T.O. sequence listing requirements. Specifically, the replacement sequence listing adds SEQ ID NOs: 50 and 51. The full 980 amino acid sequence of SEQ ID NO: 50, which corresponds to ProNectin F is:

MDPVVLQRRDWENPGVTQLNRLAAHPPFASDPMGAGS$(GAGAGS)_6$GAAVTGRGDSPA SAAGY$[(GAGAGS)_9$GAAVTGRGDSPASAAGY$]_{12}(GAGAGS)_2$GAGAMDPGRYQLSAGRY HYQLVWCQK

The full 1019 amino acid sequence of SEQ ID NO: 51, which corresponds to ProNectin L is:

MDPVVLQRRDWENPGVTQLNRLAAHPPFASDPMGAGS$(GAGAGS)_6$GAAPGASIKVAVS AGPSAGY$[(GAGAGS)_9$GAAPGASIKVAVSAGPSAGY$]_{12}(GAGAGS)_2$GAGAMDPGRYQLS AGRYHYQLVWCQK

Additionally, Applicants herewith submit evidence that ProNectins F and L recited in the specification were, at the time of filing, represented by SEQ ID NOs: 50 and 51, respectively. Please see "Handbook of Biodegradable Polymers," Harwood Academic Publishers, Amsterdam

p. 387-414 (1997), which is attached hereto. This document was cited by the Japanese Patent Office in JP 2003-304868A and JP 2004-49921A, both of which were previously submitted in an Information Disclosure Statement. The Examiner's attention is drawn to the section entitled "ProNectin Protein Polymers" on pages 393-395, as well as the table on page 413. It is noted that in this document, ProNectin F is also known as "SLPF" and ProNectin L is also known as ProNectin SLPL3.0. Furthermore, the content of ProNectins F and L is also confirmed by Watabe *et al.*, which is also attached. The Examiner's attention is drawn to section "2.1. Recombinant cell adhesive proteins" on page 248, where ProNectins F and L are both identified as having the exact same content as SLPF and SLPL3.0 in the "Handbook of Biodegradable Polymers."

Additionally, Applicants discuss the difference between the molecular weights of ProNectin F (72,738) and ProNectin L (75,639) in the attached documents as compared with the molecular weights of ProNectin F (110,000) and ProNectin L (110,000) in the specification. In the attached documents, the molecular weights were calculated based on the sequences of SLPF (ProNectin F) and SLPL3.0 (ProNectin L). On the other hand, in the specification, the molecular weights are the weight average molecular weights (Mw) as determined by fractionating a sample by SDS-PAGE and comparing the migration distance thereof with that of a standard substance. See page 8, lines 38-34. Thus, the difference is due to the different ways in which the molecular weight was determined—by calculation vs. by experiment. Accordingly, it is clear that SLPF and SLPL3.0 of the "Handbook of Biodegradable Polymers" are ProNectin F and ProNectin L,

respectively. Thus, the replacement sequence listing does not add new matter. Applicants herein amend the claims in order to refer to SEQ ID NO: 50 and 51.

Election/Restriction

It is the position of the Office Action that claims 13 and 14 are directed to an invention that is independent or distinct from the invention originally claimed. The Office Action notes that Applicants previously elected Arg-Gly-Asp as (X), Gly-Ala-Gly-Ala-Gly-Ser as (Y), and polyalkylenepolyamine as (A). Additionally, the Office Action states that the recitation of specific peptides by trademark names (such as ProNectin F, ProNectin F2, etc.) "lacks antecedent basis in the base claim." As a result of the above, the Office Action states that the originally presented invention was constructively elected, and that claims 13 and 14 are withdrawn from consideration.

First, Applicants herein cancel claim 13. Additionally, claims 1 and 14 are herein amended in order to recite SEQ ID NO: 50, which corresponds to ProNectin F. Thus, claim 14 does in fact recite elected subject matter. As explained on page 9, lines 4-11, ProNectin F is a peptide having Arg-Gly-Asp as (X) and $(Gly\text{-}Ala\text{-}Gly\text{-}Ala\text{-}Gly\text{-}Ser)_9$ as (Y). In ProNectin F, these sequences are chemically bonded to each other in an alternating fashion. In other words, ProNectin F is a commercial embodiment of the polypeptide of claim 1 and 14. Thus, these claims recite elected subject matter.

Applicants' Response to Claim Rejections under 35 U.S.C. §112

Claims 2 and 3 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that there is insufficient antecedent basis for the term "repeated" in claims 2 and 3. Applicants herein cancel claims 2 and 3. Thus, this rejection is moot.

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

It is the position of the Office Action that claims 1-7 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. It appears that the Office Action identifies two issues with the claims: (i) that the specification does not support the numerous species encompassed by the claims, and (ii) that the claims encompass unknown structural features.

As noted above, Applicants herein amend the claims in order to refer to the full length sequences of ProNectin F and L. Please see amended claims 1 and 14 and new claim 15, which refer to SEQ ID NO: 50 and 51. Thus, Applicants respectfully submit that the pending claims fully comply with all requirements of 35 U.S.C. §112. Favorable reconsideration is respectfully requested.

Applicants' Response to Claim Rejections under 35 U.S.C. §103

Claims 1-7, 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ferrari et al. (U.S. Patent No. 6,184,348) in view of Cook et al. (U.S. Patent No. 5,916,585) and Lin et al. (Journal of Biomedical Material Research, 28, 329-342, 1994).

It is the position of the Office Action that Ferrari discloses the invention as claimed, with the exception of (i) the use of polyalkylenepolyamine or polyarylenepolyamine matrices and (ii) covalent bonding between the peptide and the polymer sheet. The Office Action relies on Cook to provide the teaching of (i) the use of polyalkylenepolyamine or polyarylenepolyamine matrices. The Office Action relies on Lin to provide the teaching of (ii) attaching the polypeptide to the polymer sheet by covalent bonding.

Ferrari relates to a recombinantly produced proteinaceous polymer composition. As the Office Action recognizes, Ferrari does not teach the use of a polyalkylenepolyamine and/or polyarylenepolyamine. Moreover, Ferrari describes that the "subject material may be made into or coated on woven fabrics, films or membranes," as recognized by the Office Action. However, Ferrari does not describe the kinds of films or membranes or even suggest polyurethane as a sheet. Furthermore, as recognized by the Office Action, Ferrari does not disclose that a polypeptide and a sheet are bonded by a covalent bonding. In addition, Ferrari does not disclose that acceleration of epidermal regeneration and rapid cure of wounds can be obtained by using the wound dressing having the claimed constitution.

Cook relates to a biodegradable material for immobilization of bioactive species thereon, the material comprising a porous hydrophobic biodegradable support member and a first layer

comprised of at least one species of a polymeric surfactant, and wherein the surfactant is cross-linked to itself with a cross-linking agent. Cook discloses that the bioactive species are immobilized directly to chemical functional groups of the first layer as shown in the Figures. Namely, the bioactive species are immobilized not to the hydrophobic support member, but to the first layer comprised of a surfactant. Thus, as the Office Action recognizes, Cook does not disclose that the bioactive species and the hydrophobic support member are bonded by a covalent bonding. Moreover, Cook does not disclose that acceleration of epidermal regeneration and rapid cure of wounds can be obtained by using the wound dressing of the present invention having the above specific constitution.

Lin only describes the synthesis, surface and cell-adhesion properties of polyurethane containing covalently graft RGD-peptides. In Lin, the RGD-containing peptide is merely grafted to the polymer backbone. Namely, Lin does not disclose the wound dressing of the claimed embodiments in which the polypeptide (P) and the polyurethane sheet (S) are bonded by covalent bonding. Lin only describes RGD-peptides and does not disclose the polypeptide (P) having the recited ProNectins.

Applicants respectfully submit that the disclosure of Cook is insufficient. Cook merely identifies polyethyleneimine as one of many polymeric surfactants. Additionally, the Office Action cites Cook's reference to RGD at column 6, line 60. However, in this passage, RGD is only listed as one of many possible targets of immobilization. Applicants respectfully submit that Cook's disclosure of polyethyleneimine and RGD are not a sufficient disclosure.

Although a reference is prior art for all that it teaches, Applicants respectfully submit that the teachings of Cook are limited to an invitation to investigate. Specifically, Applicants respectfully submit that the listing of over 18 possible polymeric surfactants and dozens of immobilization targets in Cook is not an enabling disclosure, but merely an invitation to investigate. According to MPEP §2121.01, "[t]he disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation."

Cook does not provide guidance as to which of these polymeric surfactants or immobilization targets is likely to be effective. Instead, Cook is merely an invitation to investigate these polymeric surfactants and immobilization targets. According to MPEP §2112, "'[a]n invitation to investigate is not an inherent disclosure' where a prior art reference 'discloses no more than a broad genus of potential applications of its discoveries'" (Quoting Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004). The disclosure of Cook of treatment of dozens of broad classes of diseases is merely a broad disclosure of potential applications, and not an enabling disclosure. Therefore, for at least these reasons, Applicants respectfully submit that Cook does not provide a sufficient disclosure of the recited polyamines (A).

In addition, Applicants respectfully submit that the experimental data in the present specification provides evidence for unexpected results by using the specific polyamine (A) such as polyethyleneimine, as compared with other surfactants such as poly-lysine. The Examples,

Comparative Examples (especially wound dressings HB3-HB6) and Table 1 on page 34 of the specification show that the specific polyamine (A) provides unexpected results as compared with other compounds such as poly-L-lysine and poly(dimethylamino ethyl methacrylate).

Accordingly, even if Ferrari, Cook and Lin are combined, the combination of references does not disclose or suggest that the unexpected excellent results of the acceleration of epidermal regeneration and rapid cure of wounds can be obtained by using a wound dressing having the claimed constitution. Therefore, the covalent bonding of the peptide with the matrix is not "the product not of innovation but of ordinary skill and common sense." As such, the claimed embodiments would not have been obvious to one having ordinary skill in the art from the cited references. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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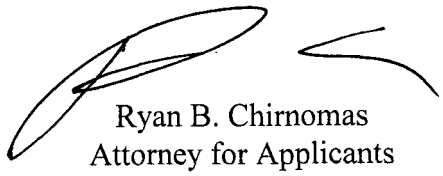

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RBC/nrp

Enclosures: "20. Genetically Engineered Protein Polymers." Joseph Cappello. *Handbook of Biodegradable Polymers*, Harwood Academic Publishers, Amsterdam, pages 387-414 (1997).
"Influences of the recombinant artificial cell adhesive proteins on the behavior of human umbilical vein endothelial cells in serum-free culture." A. Ishii-Watabe *et al.*, Biologicals, 35 (2007) 247-257.